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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/782,378	02/18/2004	Bruce K. Redding JR.	04-40080-US (879388.20001	3551

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EXAMINER	
GRAY, PHILLIP A	

ART UNIT	PAPER NUMBER
3767	

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10/09/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/782,378	REDDING, BRUCE K.	
	Examiner	Art Unit	
	Phillip Gray	3767	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *7/16/2007*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-20* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-20* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

This Office Action is in response to applicant's communication filed on 7/16/2007. Currently amended and newly added claims 1-20 are pending and rejected.

Response to Arguments

Applicant's arguments with respect to claims 1-20 have been considered but are moot in view of the new ground(s) of rejection.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claim 1, 9-10, and 19-20 rejected under 35 U.S.C. 102(b) as being anticipated by Rowe et al. (U.S. 6,234,990). Rowe discloses a substance delivery device and associated method comprising an apparatus containing the substance to be delivered and positioned adjacent tissue (see apparatus in figure 10), at least one ultrasonic transducer (134) sonically coupled to the substance containing apparatus, and at least one sensor positioned with a transducer wherein said ultrasonic transmissions received by the sensor is indicative of substance actually liberated from the substance containing apparatus (see sensor disclosure and teachings at Rowe paragraphs at column 12 line 1 through column 13 line 46) and a controller device (such as figure 8 and element 90).

It is further examiners position that the controller means of Rowe would satisfy the functional/operational claim limitations as in claims 19 and 20 of measuring the amount of substance delivered based on reflected ultrasonic transmissions, and

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a)..

Claim 2 is rejected under 35 U.S.C. 103(a) as being unpatentable over Rowe, in view of Shimada et al. (U.S. Patent number 5,267,985). Rowe discloses the claimed invention except for the ultrasound frequency transmission in the range of about 20 KHz to 30 MHz. Shimada teaches that it is known to use ultrasound frequency

transmissions in the range of 1hz to 100 MHz for therapeutic or diagnostic ultrasound, (as set forth in Column 5,Line 39 through Column 7, Line 13) to provide "optimum diffusion of the drug across the stratum corneum while maximizing penetration of a drug or other substance into the local area of target tissue". It would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the ultrasonic transducer as taught by Rowe to operate in a 1hz to 100 MHz frequency range as taught by Shimada, since such a modification would provide the ultrasonic transducer with a 1hz to 100 MHz frequency range to provide for effective and efficient diffusion of drugs into a given tissue.

Claims 3 through 8 are rejected under 35 U.S.C. 103(a) as being unpatentable over Rowe in view of Dellagatta (U.S. Patent number 5,954,675). Rowe discloses the claimed invention except for the ultrasonic intensity range and alternating, pulsed, or continuous waveform. Dellagatta teaches that it is known to use an ultrasonic intensity range up to 3.0 W/sq. cm. (Column 3, Line 7) to foster hydration of the stratum corneum (Column 3, Line 47). It would have been obvious of one having ordinary skill in the art at the time the invention was made to modify the ultrasonic transducer as taught by Rowe with a 0 to 3.0 W/sq. cm. intensity range as taught by Dellagatta, since such a modification would provide the ultrasonic transducer with a 0 to 3.0 W/sq. cm. Ultrasonic transmission intensity range for providing hydration of the tissue that is receiving the ultrasonic signals.

Further Dellagatta discloses that it is known to use an alternating, pulsed or continuous waveform (Column 1, Line 14) as a preferred treatment where heat

exacerbates pain in the patient, or when only non-thermal, mechanical effects of ultrasound, e.g. enhancement of tissue regeneration, are desired. It would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the ultrasonic transducer's waveform as taught by Rowe with an alternating, pulsed, or continuous waveform as taught by Dellagatta, since such a modification would provide the transducer's waveform with and alternating, pulsed, or continuous waveform, for providing treatment without heat and a mechanical therapy for pain management and tissue regeneration.

It is noted that Rowe in further view of Dellagatta discloses the claimed invention except for specifically referencing a "sawtooth" waveform or a "square" waveform. It would have been obvious to one having ordinary skill in the art at the time the invention was made that the alternating waveform produced by the ultrasonic transducer included both "square" or "sawtooth" waveforms, since it was known in the art that "square" or "sawtooth" waveforms are typical types of alternating waveforms for enhanced measured efficient ultrasonic transmission delivery.

Claim 11 is rejected under 35 U.S.C. 103(a) as being unpatentable over Rowe in view of Shimada (5,267,985). Rowe discloses the claimed method except for the ultrasound frequency transmission in the range of about 20 KHz to 30 MHz. Shimada teaches that it is known to use ultrasound frequency transmissions in the range of 1hz to 100 MHz for therapeutic or diagnostic ultrasound, (as set forth in Column 5,Line 39 through Column 7, Line 13) to provide "optimum diffusion of the drug across the stratum corneum while maximizing penetration of a drug or other substance into the local area

of target tissue". It would have been obvious to one having ordinary skill in the art at the time the method was made to modify the transdermal substance delivery method as taught by Rowe to operate in a 1hz to 100 MHz frequency range as taught by Shimada, since such a modification would provide the transdermal substance delivery method with a 1hz to 100 MHz frequency range to provide for effective and efficient diffusion of drugs into a given tissue.

Claims 12 through 17 are rejected under 35 U.S.C. 103(a) as being unpatentable over Rowe in further view of Dellagatta (5,954,675). Rowe discloses the claimed method except for the ultrasonic intensity range and alternating, pulsed, or continuous waveform. Dellagatta teaches that it is known to use an ultrasonic intensity range up to 3.0 W/sq. cm. (Column 3, Line 7) to foster hydration of the stratum corneum (Column 3, Line 47). It would have been obvious of one having ordinary skill in the art at the time the invention was made to modify the transdermal drug delivery method as taught by Rowe with a 0 to 3.0 W/sq. cm. intensity range as taught by Dellagatta, since such a modification would provide the transdermal drug delivery method with a 0 to 3.0 W/sq. cm. Ultrasonic transmission intensity range for providing hydration of the tissue that is receiving the ultrasonic signals.

Further Dellagatta discloses that it is known to use an alternating, pulsed or continuous waveform (Column 1, Line 14) as a preferred treatment where heat exacerbates pain in the patient, or when only non-thermal, mechanical effects of ultrasound, e.g. enhancement of tissue regeneration, are desired. It would have been obvious to one having ordinary skill in the art at the time the invention was made to

modify the transdermal delivery method as taught by Rowe with an alternating, pulsed, or continuous waveform as taught by Dellagatta, since such a modification would provide the transdermal delivery method with and alternating, pulsed, or continuous waveform, for providing treatment without heat and a mechanical therapy for pain management and tissue regeneration.

It is noted that Rowe in view of Dellagatta discloses the claimed invention except for specifically referencing a "sawtooth" waveform or a "square" waveform. It would have been obvious to one having ordinary skill in the art at the time the invention was made that the alternating waveform produced by the method's ultrasonic transducer included both "square" or "sawtooth" waveforms, since it was known in the art that "square" or "sawtooth" waveforms are typical types of alternating waveforms for enhanced measured efficient ultrasonic transmission delivery.

Claim Rejections - 35 USC § 112

Claims 19 and 20 recites the limitation "said reflected ultrasonic transmissions" in the third line of the claims. There is insufficient antecedent basis for this limitation in the claim. Applicant had cancelled the "reflected" part in the ultrasonic transmissions of the independent claims, which claims 19 and 20 depend from. It is recommended that applicant amend the claims to either add the "reflected" language to the independent claim or remove the word "said" in claims 19 and 20.

Prior Art of Record

The prior art made of record and not relied upon is considered pertinent to applicant's disclosure.

U.S. Patent Number 5,445,611, Eppstein et al. discloses a method and apparatus for Enhancement of transdermal delivery with ultrasound and chemical enhancers

U.S. Patent Number 6,041,253, Kost et al. discloses a method and apparatus for effect of electrical field and ultrasound for transdermal drug delivery.

Conclusion

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of

the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Phillip Gray whose telephone number is (571) 272-7180. The examiner can normally be reached on Monday through Friday, 8:30 a.m. to 4:30 p.m. EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Kevin Sirmons can be reached on (571) 272-4965. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

PAG

KEVIN C. SIRMONS
SUPERVISORY PATENT EXAMINER